

CERTIFICATE OF ANALYSIS

**CHROMOGENIX**

PRODUCT:	Factor V Deficient Plasma	PRODUCT # :	82314663
EXP. DATE:	2005-07	LOT # :	N0147188
VENDOR:	INSTRUMENTATION LABORATORY	ASSAYED PER QCM:	H01450

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION
	MIN	MAX			
<b>APC ratio on ACL</b>					
<i>(1 part Control Plasma Level 1 + 4 parts V-Def plasma)</i>					
APT Time	--	38	seconds	32	PASS
APC Ratio	2.3	3.0	--	2.8	PASS
<i>(1 part heterozygous plasma @ 1IU Heparin/ml + 4 parts V-Def plasma)</i>					
APT Time	--	38	seconds	34	PASS
APC Ratio	1.4	1.9		1.8	PASS
<i>(1 part homozygous plasma + 4 parts V-Def plasma)</i>					
APT Time	--	38	seconds	33	PASS
APC Ratio	--	1.4		1.3	PASS
<b>Factor V Content (on ST-4)</b>					
Factor V Content	--	4.5	%	0.6	PASS
<b>Residual Moisture</b>					
H <sub>2</sub> O Content	--	5	%	1	PASS

DESCRIPTION	LOT NUMBER	EXP. DATE	VOLUME
Factor V Deficient Plasma	N0147188	2005-07	4 ml (x 5)

We hereby certify that the above product(s):  
 - have been manufactured and tested according to the requirements of their Manufacturing and Quality Control procedures and have been found to meet all conditions set forth with these documents.  
 - meet all applicable requirements of the 98/79/EC Directive according to which they are CE marked.

PREPARED BY: D. Teneza DATE: 06/10/04

APPROVAL SIGNATURE: J. Facciola DATE: 06/10/04